

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMGEN INC.,

Plaintiff,

v.

APOTEX INC.,

Defendant.

C.A. No. 3:22-cv-03827-MAS-DEA

Hon. Michael A. Shipp, U.S.D.J.

Hon. Douglas E. Arpert, U.S.M.J.

STIPULATION AND ORDER

Plaintiff Amgen Inc. (“Amgen”) and Defendant Apotex Inc. (“Apotex”), the parties in the above-captioned action, hereby stipulate to the entry of an order and injunction in this action, as follows:

IT IS this 20th day of January, 2023:

ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of the above action and has personal jurisdiction over the parties for purposes of this action only, including as set forth below in Paragraph 8 and Paragraph 9 of this Stipulation And Order.

2. As used in this Stipulation And Order, the term “Apotex ANDA Product” shall mean a drug product manufactured, used, offered for sale, sold, or imported pursuant to Abbreviated New Drug Application No. 217258 (“Apotex ANDA”).

3. As used in this Stipulation And Order, the term “Patents-in-Suit” shall mean U.S. Patent Nos. 7,427,638, 9,872,854, and 10,092,541.

4. As used in this Stipulation And Order, the term “Affiliate” shall mean any entity or person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with Apotex; for purposes of this definition, “control” (including the terms “controlled by” and “under common control with”) of a business entity means (a) the direct or indirect ownership of more than fifty percent (50%) of the voting stock or other voting interest in such entity; (b) the right to appoint more than fifty percent (50%) of the directors or management of such entity; or (c) the power to otherwise control or direct the decisions of the board of directors or similar body governing the affairs of such entity, provided that such other person shall be deemed an Affiliate of such first person only during the time that such control exists.

5. Apotex has admitted, for itself and its Affiliates, solely with respect to the Apotex ANDA and the Apotex ANDA Product, that the Patents-In-Suit are valid and enforceable.

6. Apotex has admitted, for itself and its Affiliates, solely with respect to the Apotex ANDA and the Apotex ANDA Product, that the Patents-In-Suit would be infringed by making, using, offering to sell, selling, or importing the Apotex ANDA Product.

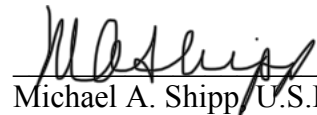
7. Until expiration of the Patents-in-Suit, including all extensions and pediatric exclusivities, and subject to 35 U.S.C. § 271(e)(1), Apotex, including its Affiliates, successors and assigns, is enjoined from infringing the Patents-in-Suit, on its own part or through any Affiliate or any third party on its behalf, by making, using, selling, offering to sell, or importing the Apotex ANDA Product and is further enjoined from assisting or cooperating with any third parties in connection with any infringement of the Patents-in-Suit by any such third parties, except as and to the extent specifically authorized by Amgen in writing.

8. Compliance with this Stipulation And Order may be enforced by Amgen and its respective successors in interest or assigns.

9. This Court retains jurisdiction to enforce the terms of this Stipulation And Order and to enforce and resolve any disputes related thereto.

10. All claims, counterclaims, affirmative defenses and demands in this action are hereby dismissed without prejudice and without costs, disbursements, or attorneys' fees to any party.

11. Nothing herein shall be construed as preventing the U.S. Food & Drug Administration from granting final, effective approval to the Apotex ANDA.


Michael A. Shipp/U.S.D.J.

We hereby consent to the form and entry of this Order:

s/ Charles H. Chevalier

Charles H. Chevalier
Stephen R. Donat
GIBBONS P.C.
One Gateway Center
Newark, NJ 07102-5310
(973) 596-4500

Christine A. Gaddis
GIBBONS P.C.
131 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801

George F. Pappas
Jeffrey B. Elikan
Michael N. Kennedy
Priscilla Dodson
Alexander Trzeciak
COVINGTON & BURLING LLP
One CityCenter
850 10th Street NW
Washington, DC 20001-4956
(202) 662-6000

Alexa Hansen
COVINGTON & BURLING LLP
Salesforce Tower
415 Mission Street
San Francisco, CA 94105-2533
(415) 591-7035

Wendy A. Whiteford
Eric M. Agovino
C. Nichole Gifford
Gregory Bonifield
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Attorneys for Amgen Inc.

s/ Melissa E. Flax

Melissa E. Flax
Michael K. Belostock
CARELLA, BYRNE, CECCHI, OLSTEIN,
BRODY & AGNELLO, PC
5 Becker Farm Road
Roseland, NJ 07068
(973) 994-1700

Stephen R. Auten
Philip Y. Kouyoumdjian
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
(312) 840-4313

Attorneys for Defendant Apotex Inc.